Various studies have shown that elevated systolic pressure is associated with a greater risk of heart failure, stroke, and acute myocardial infarction, and that treatment of elevated systolic pressure can delay or prevent such adverse events even when diastolic pressure is normal or low.

A number of studies have also shown that, in patients over 50, there is a stronger association between adverse cardiovascular (particularly coronary) events and pulse pressure, than systolic or diastolic pressure in isolation. Accordingly, for any given systolic pressure, the diastolic pressure is inversely related to the risk of adverse cardiovascular events, possibly due to reduction in coronary perfusion with decreased diastolic pressure.

Heart failure is reported to effect 2 to 5 percent of people in Western societies aged over 65, and 10 percent of those aged over 75. It is also reported to be the leading cause of hospital admission and readmission in Americans older than 65.

The increase in systolic blood pressure with age is largely a result of stiffening of the aorta and large elastic arteries. Dilatation of the aorta/arteries is typically associated with this stiffening. The stiffening and dilatation is a result of the repetitive cyclic stress applied to the aorta wall during expansion and subsequent relaxation of the aorta. The cyclic stresses applied to the aorta wall result in fatigue, fracture and fragmentation of the elastin fibres which provide the aorta wall with its elasticity. The mechanical properties of the aorta wall gradually become dominated by inelastic collagen. The breakdown of the elastin fibres results in the aorta becoming inelastic and stiff, thereby losing its capability to restore to its original diameter after expansion during the systole stage. The aorta accordingly remains permanently dilatated.

A young, healthy ascending aorta typically has an external diameter of the order of 25 mm when subjected to normal diastolic pressure of 70 mmHg (9.3 kPa), and a wall thickness of the order of 1 mm. The diameter and wall thickness decrease from the proximal portions of the aorta to the more distal portions. Dilatation of the aorta associated with aortic stiffening may result in an increase in the external diameter of the ascending aorta at diastolic pressure to as large as 40 mm or more. An aorta dilatated by an aneurysm may have a diameter up to 100 mm. Stiffening of the aorta is also associated with such aneurysms. When an aneurysm dilatates the aorta beyond a 60 mm diameter, usual practice is to remove the aneurysm and replace it with a synthetic graft.

Measurement of the stiffness of the aorta has been the subject of various studies, measuring various different stiffness related properties. The measurement of pure tensile

The most effective means of treating, or preventing, heart failure is to reduce cardiac load either pharmacologically or mechanically. Mechanical reduction of cardiac load using intra-aortic balloon counter pulsation and ventricular assist devices have proven effective. However, intra-aortic balloon counter pulsation can only be used as a temporary treatment. Ventricular assist devices are also expensive and temporary measures.

Object of the Invention

It is an object of the present invention to overcome or substantially ameliorate at least one of the above disadvantages.

Summary of the Invention

In a first aspect, the present invention provides a method of treating a stiffened blood vessel, the method comprising at least substantially encasing a portion of said blood vessel with an elastic membrane formed of biocompatible material such that said membrane engages said blood vessel to thereby reduce the external diameter of said blood vessel.

Preferably the blood vessel is an artery.

More preferably the blood vessel is the aorta, particularly the ascending aorta.

The portion of the blood vessel may be a grafted synthetic portion of blood vessel. The grafted synthetic portion may be a woven polyester graft. Alternatively, the grafted synthetic portion may be a polytetrafluoroethylene or Gore-Tex® graft.

The blood vessel may be dilatated prior to treatment.

The membrane may be in the form of a sheet, said blood vessel portion being encased by wrapping said membrane sheet around the circumferential periphery of said blood vessel portion and securing opposing end portions of said membrane.

The membrane sheet may be wrapped around either the entire circumferential periphery of said blood vessel portion, or only about a majority of the circumferential periphery.

The opposing end portions of said membrane sheet may be secured by suturing.

Alternatively, the opposing end portions of said membrane may be secured by way of a clamp, or by welding.

In another form, the opposing end portions of said membrane may be secured by way of interlocking structures formed on, or fixed to, each of said opposing end portions.

Each opposing end portion may be provided with a marking extending generally parallel with a free end edge of said end portion, said end portions being secured along or adjacent to said markings.

The membrane sheet may be formed by slitting a cylindrical membrane.

The membrane may be in the form of a spiral, said blood vessel portion being encased by spirally wrapping said membrane spiral around the circumferential periphery of said blood vessel portion.

Typically, said membrane has a stiffness approximating that of a non-stiffened blood vessel of the type of blood vessel being treated.

The membrane may have a measurement of tensile stiffness x thickness of between 25 and 2500 N/m, or optionally more specifically between 50 and 1000 N/m.

The membrane, when formed into a cylinder having an internal diameter of 20 mm, may have an average pressure-strain elastic modulus of between 0.15×10^6 and 15×10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa), or optionally more specifically between 0.3×10^6 and 6×10^6 dyn/cm^2.

The external diameter of the blood vessel may be reduced by between 10% and 50% when encased with said membrane, at a pressure of 70 mmHg (9 kPa)

When the blood vessel is the ascending aorta, the external diameter of the blood vessel may be reduced to between 10 and 60 mm at a pressure of 70 mmHg, or optionally more specifically between 18 and 30 mm.

The membrane may be formed of an elastic silicon polymer or elastic polyurethane material.

Preferably, said method is carried out thoracoscopically.

In a second aspect, the present invention provides a method of treating a blood vessel, said blood vessel having a native tissue portion and a synthetic portion grafted in line with said native tissue portion, said synthetic portion having a greater stiffness than the stiffness of said native tissue portion, said method comprising at least substantially encasing said synthetic portion with an elastic membrane formed of biocompatible material such that said membrane engages said synthetic portion to thereby reduce the diameter of said synthetic portion.

In a third aspect, the present invention provides a device for treating a stiffened blood vessel, said device comprising an elastic membrane formed of a sheet of biocompatible material having two opposing end portions, said membrane being adapted to be wrapped around the circumferential periphery of a portion of said blood vessel and

said opposing end portions secured to each other to thereby reduce the external diameter of said blood vessel, wherein each said end portion is provided with a marking extending generally parallel with a free end edge of said end portion, said marking being indicative of the location at which said opposing end portions are to be secured with said membrane wrapped about said blood vessel portion, the distance between said end markings being selected as the circumference of a cylinder to be formed by wrapping said membrane sheet around said blood vessel portion.

The distance between said markings may be between 31 and 188 mm (corresponding to a cylinder diameter of between 10 and 60 mm) or optionally more specifically between 56 and 94 mm (corresponding to a cylinder diameter of between 18 and 30 mm).

In a fourth aspect, the present invention provides a device for treating a stiffened blood vessel, said device comprising an elastic membrane formed of a sheet of biocompatible material having two opposing end portions, said membrane being adapted to be wrapped around the circumferential periphery of a portion of said blood vessel, wherein said device further comprises interlocking structures formed on, or fixed to, each said opposing end portion for securing said end portions about said blood vessel portions to thereby reduce the external diameter of said blood vessel.

In a fifth aspect, the present invention provides a device for treating a stiffened blood vessel, said device comprising an elastic membrane formed of a sheet of biocompatible material having two opposing end portions, said membrane being adapted to be wrapped around the circumferential periphery of a portion of said blood vessel and said opposing end portions secured to each other to thereby reduce the external diameter of said blood vessel, wherein a series of generally parallel markings are applied to a surface of said membrane.

Typically, each of said markings extends generally parallel to a free end edge of each of said end portions.

In a sixth aspect, the present invention provides a device for treating a stiffened blood vessel, said device comprising an elastic membrane formed of a sheet of biocompatible material having two opposing end portions, said membrane being adapted to be wrapped around the circumferential periphery of a portion of said blood vessel, wherein said membrane includes a radio-opaque marker.

The radio-opaque marker may be dispersed throughout said membrane.

reduced stiffness will be much more significant than the increase in pulse pressure resulting from the decreased diameter. There is thus a balance between providing a diameter reduction that is sufficient for an elastic membrane of a given reduced stiffness to take most of the pressure load for pressures from diastolic pressure up to systolic pressure, whilst not being so substantial that it adversely constricts blood flow.

The ideal combination of elastic membrane stiffness and blood vessel diameter reduction will vary dependent upon the specific application, although the stiffness of the native blood vessel will not appreciably effect this selection.

Based on the in-vitro and computational results, reductions in diastolic diameter of a blood vessel of between 10% and 50% are expected to be particularly suitable. For the ascending aorta, reductions in diastolic external diameter to between 10 mm (particularly for young humans) and 60 mm (particularly when treating an aorta with large dilatation caused by an aneurysm) at a normal diastolic pressure of 70 mmHg (9 kPa) are expected to be particularly suitable without adversely constricting the blood flow passage. For most applications, reductions in diastolic external diameter of the ascending aorta to between 18 and 30 mm will be particularly suitable.

A measurement of elastic membrane tensile stiffness x thickness of between 25 and 2500 N/m is also expected to be suitable when treating the aorta, particularly the ascending aorta, with measurements between 50 and 1000 N/m being particularly suitable.

Considering the average pressure-strain elastic modulus of the membrane itself, a modulus of between 0.15×10^6 and 15×10^6 dyn/cm^2 for a cylinder formed of the membrane with an internal diameter of 20 mm at a pulsatile pressure of 120/70 mmHg (16/9 kPa) is expected to be suitable, with a modulus of between 0.3×10^6 and 6×10^6 dyn/cm^2 being particularly suitable.

The computational modelling has also established that the procedure of encasing a blood vessel with an elastic membrane is most effective when applied to the ascending aorta. Whilst improvements are achieved by encasing other stiffened blood vessels, particularly other portions of the aorta, the reductions in pulse pressure are much less than those that can be achieved by encasing the ascending aorta. The ascending aorta is also free of intercostal artery branches, and hence it is also a very suitable blood vessel for encasing in terms of surgical simplicity, as a single sheet membrane can be readily applied to the ascending aorta. The modelling further indicated that there is little

CLAIMS:

1. A method of treating a stiffened blood vessel, said method comprising at least substantially encasing a portion of said blood vessel with an elastic membrane formed of biocompatible material such that said membrane engages said blood vessel to thereby reduce the external diameter of said blood vessel.

2. The method of claim 1 wherein said blood vessel is an artery.

3. The method of claim 2 wherein said blood vessel is the aorta

4. The method of claim 2 wherein said blood vessel is the ascending aorta.

5. The method of claim 1 wherein said portion of said blood vessel is a grafted synthetic portion of said blood vessel.

6. The method of claim 5 wherein said grafted synthetic portion is a woven polyester graft.

7. The method of claim 1 wherein said blood vessel is dilatated prior to treatment.

8. The method of claim 1 wherein said membrane is in the form of a sheet, said blood vessel portion being encased by wrapping said membrane sheet around the circumferential periphery of said blood vessel portion and securing opposing end portions of said membrane.

9. The method of claim 8 wherein said membrane sheet is wrapped around the entire circumferential periphery of said blood vessel portion.

10. The method of claim 8 wherein said membrane sheet is wrapped about a majority of the circumferential periphery of said blood vessel portion.

11. The method of claim 8 wherein the opposing end portions of said membrane sheet are secured by suturing.

12. The method of claim 8 wherein the opposing end portions of said membrane are secured by way of a clamp.

13. The method of claim 8 wherein the opposing end portions of said membrane are secured by welding.

14. The method of claim 8 wherein the opposing end portions of said membrane are secured by way of interlocking structures formed on, or fixed to, each of said opposing end portions.

15. The method of claim 8 wherein each opposing end portion is provided with a marking extending generally parallel with a free end edge of said end portion, said end portions being secured along or adjacent to said markings.

16. The method of claim 8 wherein said membranc sheet is formed by slitting a cylindrical membrane.

17. The method of claim 1 wherein said membrane is in the form of a spiral, said blood vessel portion being encased by spirally wrapping said membrane spiral around the circumferential periphery of said blood vessel portion.

18. The method of claim 1 wherein said membrane has a stiffness approximating that of a non-stiffened blood vessel of the type of blood vessel being treated.

19. The method of claim 1 wherein said membrane has a measurement of tensile stiffness x thickness of between 25 and 2500 N/m.

20. The method of claim 19 wherein said measurement of tensile stiffness x thickness is between 50 and 1000 N/m.

21. The method of claim 8, wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.15×10^6 and 15×10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

22. The method of claim 8, wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.3×10^6 and 6×10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

23. The method of claim 1 wherein said external diameter of said blood vessel is reduced by between 10% and 50% when encased with said membrane, at a pressure of 70 mmHg (9 kPa)

24. The method of claim 4 wherein said external diameter of said blood vessel is reduced to between 10 mm and 60 mm at a pressure of 70 mmHg (9kPa)

25. The method of claim 4 wherein said external diameter of said blood vessel is reduced to between 18 mm and 30 mm at a pressure of 70 mmHg (9kPa)

26. The method of claim 1 wherein said membrane is formed of an elastic silicon polymer.

27. The membrane of claim 1 wherein said membrane is formed of an elastic polyurethane.

28. The method of claim 1 wherein said method is carried out thoracoscopically.

29. A method of treating a blood vessel, said blood vessel having a native tissue portion and a synthetic portion grafted in line with said native tissue portion, said synthetic portion having a greater stiffness than the stiffness of said native tissue portion, said method comprising at least substantially encasing said synthetic portion with an elastic membrane formed of biocompatible material such that said membrane engages said synthetic portion to thereby reduce the external diameter of said synthetic portion.

30. The method of claim 29 wherein said synthetic portion is a woven polyester.

31. A device for treating a stiffened blood vessel, said device comprising an elastic membrane formed of a sheet of biocompatible material having two opposing end portions, said membrane being adapted to being wrapped around the circumferential periphery of the portion of said blood vessel and said opposing end portions secured to each other to thereby reduce the external diameter of said blood vessel, wherein each said end portion is provided with a marking extending generally parallel with a free end edge of said end portion, said marking being indicative of the location at which said opposing end portions are to be secured with said membrane wrapped about said blood vessel portion, the distance between said markings being selected as the circumference of a cylinder to be formed by wrapping said membrane sheet around said blood vessel portion.

32. The device of claim 31 wherein said membrane has a stiffness approximating that of a non-stiffened blood vessel of the type of blood vessel to be treated.

33. The device of claim 31 wherein said membrane has a measurement of tensile stiffness x thickness of between 25 and 2500 N/m.

34. The device of claim 33 wherein said measurement of tensile stiffness x thickness is between 50 and 1000 N/m.

35. The device of claim 31 wherein said distance between said markings is between 31 and 188 mm.

36. The device of claim 35 wherein said distance between said markings is between 56 and 94 mm.

37. The device of claim 31 wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.15×10^6 and 15×10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

38. The device of claim 31 wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.3 x 10^6 and 6 x 10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

39. The device of claim 31 wherein said membrane is formed of an elastic silicon polymer.

40. The device of claim 31 wherein said membrane is formed of an elastic polyurethane.

41. A device for treating a stiffened blood vessel, said device comprising an elastic membrane formed of a sheet of biocompatible material having two opposing end portions, said membrane being adapted to being wrapped around the circumferential periphery of the portion of said blood vessel, wherein said device further comprises interlocking structures formed on, or fixed to, each said opposing end portion for securing said end portions about said blood vessel portions to thereby reduce the external diameter of said blood vessel.

42. The device of claim 41 wherein said membrane has a stiffness approximating that of a non-stiffened blood vessel of the type of blood vessel being treated.

43. The device of claim 41 wherein said membrane has a measurement of tensile stiffness x thickness of between 25 and 2500 N/m.

44. The device of claim 43 wherein said measurement of tensile stiffness x thickness is between 50 and 1000 N/m.

45. The device of claim 41 wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.15 x 10^6 and 15 x 10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

46. The device of claim 41 wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.3 x 10^6 and 6 x 10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

47. The device of claim 41 wherein said membrane is formed of an elastic silicon polymer.

48. The device of claim 41 wherein said membrane is formed of an elastic polyurethane.

49. A device for treating a stiffened blood vessel, said device comprising an elastic membrane formed of a sheet of biocompatible material having two opposing end portions, said membrane being adapted to being wrapped around the circumferential periphery of the portion of said blood vessel and said opposing end portions secured to each other to thereby reduce the external diameter of said blood vessel, wherein a series of markings are applied to a surface of said membrane.

50. The device of claim 49 wherein each of said markings extends generally parallel to a free end edge of each of said end portions.

51. The device of claim 90 wherein said membrane has a stiffness approximating that of a non-stiffened blood vessel of the type of blood vessel being treated.

52. The device of claim 49 wherein said membrane has a measurement of tensile stiffness x thickness of between 25 and 2500 N/m.

53. The device of claim 52 wherein said measurement of tensile stiffness x thickness is between 50 and 1000 N/m.

54. The device of claim 49 wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.15×10^6 and 15×10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

55. The device of claim 49 wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.3×10^6 and 6×10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

56. The device of claim 49 wherein said membrane is formed of an elastic silicon polymer.

57. The device of claim 49 wherein said membrane is formed of an elastic polyurethane.

58. A device for treating a stiffened blood vessel, said device comprising an elastic membrane formed of a sheet of biocompatible material having two opposing end portions, said membrane being adapted to being wrapped around the circumferential periphery of the portion of said blood vessel and said opposing end portions secured to each other to thereby reduce the external diameter of said blood vessel, wherein said membrane includes a radio-opaque marker.

59. The device of claim 58 wherein said radio-opaque marker is dispersed throughout said membrane.

60. The device of claim 58 wherein said radio-opaque marker is applied to a surface of said membrane.

61. The device of claim 58 wherein said membrane has a stiffness approximating that of a non-stiffened blood vessel of the type of blood vessel being treated.

62. The device of claim 58 wherein said membrane has a measurement of tensile stiffness x thickness of between 25 and 2500 N/m.

63. The device of claim 62 wherein said measurement of tensile stiffness x thickness is between 50 and 1000 N/m.

64. The device of claim 58 wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.15 x 10^6 and 15 x 10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

65. The device of claim 58 wherein said membrane, when formed into a cylinder having an internal diameter of 20 mm, has an average pressure-strain elastic modulus of between 0.3 x 10^6 and 6 x 10^6 dyn/cm^2 at a pulsatile pressure of 120/70 mmHg (16/9 kPa).

66. The device of claim 58 wherein said membrane is formed of an elastic silicon polymer.

67. The device of claim 58 wherein said membrane is formed of an elastic polyurethane.